and 9 have been amended. Reconsideration and allowance of the present claims are hereby respectfully urged.

Briefly, the presently claimed invention relates to a soluble recombinant protein corresponding to human tumor necrosis factor binding protein I (TBP-I) and methods for recombinant production of such a recombinant protein.

The examiner points out in the first paragraph on page 2 of the Office Action that the priority date has been deemed by the examiner to be July 12, 1990, due to an alleged lack of support for the present claims in the priority Israeli patent 092697, filed December 13, 1989, such that the examiner holds that the priority date is limited to Israeli patent 095064, filed July 12, 1990.

Applicants would respectfully point out that the present application (as pointed out by the examiner on page 3), is a continuation-in-part of, and claims priority from, U.S. application Serial No. 07/243,092, filed September 12, 1988. The declaration and power of attorney filed April 26, 1991, specifically claims benefit of priority under 35 U.S.C. § 120 for this earlier filed, co-pending application in addition to the 35 U.S.C. § 119 priority claims to Israeli patents 92697, filed December 13, 1989, and 95064, filed July 12, 1990.

Applicants would respectfully point out that the

recombinant expression of TBP is fully disclosed in the parent application Serial No. 243,092 (hereinafter, "'092"), as well as the earlier Israeli patent application Serial No. 92697. As explained in greater detail below, the present claims are fully enabled and described in the parent U.S. application 243,092, filed September 12, 1988, such that the present claims are entitled to benefit of this effective filing date according to 35 U.S.C. § 120.

In particular, the parent '092 application provides a detailed description and enabling disclosure for the recombinant expression and isolation of the presently claimed tumor necrosis factor binding protein, e.g., at pages 21-32, under the section entitled "Genetic Engineering of the TNF Inhibitory Protein". Note that the TNF inhibitory protein disclosed in the '092 parent corresponds to the same TBP-I protein in the present claims.

Based on the disclosed and exemplified antibodies and N-terminal amino acid sequence presented of TBP-I, e.g., at the top of page 21 of the '092 parent application, the parent application describes in detail the cloning of TNF binding protein I using alternative cloning approaches known in the art as of the filing date of the parent application, including the use of TNF inhibitory protein specific monoclonal or polyclonal antibodies (e.g., as presented at pages 21-23); and

the use of synthetic oligonucleotides corresponding to portions of the N-terminal amino acid sequence (e.g., at pages 23-28).

Once the skilled artisan had the N-terminal amino acid sequence or monoclonal antibodies specific for the presently claimed TBP-I protein, DNA encoding the TBP-I or related proteins could be cloned without undue experimentation, based on the teachings and guidance presented in the parent '092 application.

Specific enabling description of the presently claimed methods and recombinant protein is provided in the parent application, e.g., at pages 21-30, which also includes the preparation of antibodies; screening of TNF inhibitory protein producing cells; preparation of small cDNA from the TNF inhibitory protein producing cell; preparation of genomic DNA or cDNA; the production of suitable oligonucleotide probes; screening hybridization; expression of the vectors, regulatory sequences and hosts.

Accordingly, the present claims are fully enabled and described by the parent '092 application, such that the present claims are entitled to the benefit of the effective filing date, under 35 U.S.C. § 120, of September 12, 1988. The presently claimed invention is fully described and enabled by the parent '092 application, under 35 USC 112, first

paragraph.

Additionally, oligonucleotide cloning and monoclonal MAb expression cloning, as enabled and described in the parent and present application, to obtain TBP-I characterized recombinant proteins and methods thereof, as presently claimed, could be obtained according to known method steps (see, e.g., Ausubel, eds., Current Protocols in Molecular Biology, Wiley Interscience, New York (1987); Sambrook et al, Molecular Cloning: A Laboratory Manual, 2nd Edition, Cold Spring Harbor Press, Cold Spring Harbor, NY (1989)), which were known prior to the effective filing date of the present specification.

It is also respectfully pointed out that the scope of the claims is not limited by the scope of the examples, and in fact, it has been held by the CAFC in In re Marzocchi, 169 USPQ 367, 369 (CCPA 1971):

> The only relevant concern of the Patent Office under these circumstances should be over the truth of any such assertion. The first paragraph of § 112 requires nothing more than objective enablement. How such a teaching is set forth, either by the use of illustrative examples or by broad terminology, is of no importance.

The general position of the Federal Circuit has been described in In re Robins, 166 USPQ 552, 555 (CCPA 1970) stating:

> If the examiner and/or the board intended a

> rejection under the first paragraph of § 112, it must be reversed inasmuch as the specification contains the statement of ... invention which is as broad as appellant's broadest claims, and inasmuch as the sufficiency of the specification ... to enable one skilled in the art to practice appellant's process as broadly as it is claimed has not been questioned.
>
> ... Similarly representative examples are not required by the statute and are not an end in themselves. Rather they are a means by which certain requirements of the statute may be satisfied. Thus, inclusion of a number of representative examples in the specification is one way of demonstrating the operability of a broad chemical invention and hence, establishing the utility requirement of § 101 has been met. It is also one way of teaching how to make and/or how to use the claimed invention, thus satisfying that aspect of § 112.

The enabling character of an application lacking working examples was upheld, e.g., In re Strahilevitz, 212 USPQ 561-563 (CCPA 1982).

Thus, the presently claimed TBP-I characterized recombinant protein and method can be obtained without working examples, without undue experimentation, based on the teaching and guidance presented in the parent specification.

Accordingly, reconsideration and acknowledgement of benefit of an effective filing date of September 12, 1988, for parent application '092 are respectfully urged.

Claims 1, 2 and 6-8 are rejected under 35 U.S.C. 102(a) as being anticipated by Loetscher et al. (April 20,

1990) or Schall et al. (April 20, 1990).

Applicants submit that this rejection is rendered moot by the effective priority date of the present application of September 12, 1988, such that the cited references were not available as citable art before the effective filing date of the present application. Reconsideration and withdrawal of this rejection are respectfully urged.

Claims 3 and 4 are rejected under 35 U.S.C. 103 as being unpatentable over Loetscher et al. or Schall et al. in view of Sambrook et al.

Applicants submit that this rejection is rendered moot by the effective priority date of the present application of September 12, 1988, such that the primary cited references were not available as citable art before the effective filing date of the present application. Reconsideration and withdrawal of this rejection are respectfully urged.

Claims 5 and 9 are rejected under 35 U.S.C. 103 as being unpatentable over Loetscher et al. or Schall et al.

Applicants submit that this rejection is rendered moot by the effective priority date of the present application of September 12, 1988, such that the cited references were not available as citable art before the effective filing date of the present application. Reconsideration and withdrawal of this rejection are respectfully urged.

**In re: USSN 07/625,668**

The specification is objected, and claims 1-9 are rejected, under 35 U.S.C. 112, first paragraph, for lack of enablement of analogs of TNF-BP. Claims 1-9 are also rejected under 35 U.S.C. 112, second paragraph, as being indefinite for the recitation of the terms "analog" or "precursor of TNF-BP".

Applicants have amended the claims to delete these terms, and therefore request reconsideration and withdrawal of this rejection.

It is submitted that all of the claims now present in the case clearly define over the reference of record. Reconsideration and allowance are therefore earnestly solicited.

Respectfully submitted,

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